SCIENTIFIC COMMENTS CRITICAL OF
THE DRAFT EPA ETS RISK ASSESSMENT
(Filed with EPA in Docket EPA/600/6-90/006A)

NAME

B. Schneider, PhD
Medizinische Hochschule Hannover
Institut fur Biometrie
Zentrum Biometrie, Medizinische Informatik
and Medizintechnik
Postfach 61 01 80
D-3000 Hannover 61

DATE: 8/6/90

COMMENT:

Schneider takes issue with the conclusion "that passive smoking is causally associated with lung cancer in adults." His 8-page comment demonstrates the studies' failures to achieve a significant global association between ETS and lung cancer. He notes that the "significant" study results are based on multiple testing without adjustment of selected effects and significance level. He goes on to assert that with a correct hierarchical testing procedure, "no significant association is revealed and therefore the statement of causality is lacking in empirical basis."

NAME

John P. Toutonghi, PhD
Seattle University
Department of Physics
Seattle, WA 98122

DATE: 8/14/90

COMMENT:

Toutonghi criticizes the draft for treating the Garfinkel study too lightly. He claims EPA should accept "the obvious conclusion" of Garfinkel's work and thereby concede that in the U.S. no causal link between ETS and lung cancer has been established.

2501361432

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Ragnar Rylander, MD
Professor in Environmental Hygiene
University of Gothenburg
Box 33031
400 33 Gothenburg, Sweden

DATE: None

COMMENT:

Rylander, whose background is in toxicological and epidemiological work on effects of environmental substances on the lung, provides comments of three types. He notes textual omissions of relevant studies and citations. He discusses biological plausibility, concluding that the arguments for biological plausibility in the draft do not reflect a critical scientific evaluation of the different toxicological and epidemiological concepts. Finally, he discusses the importance of the diet in preventing lung cancer.

NAME

Dr. Angelo Cerioli
Istoconsult
26012 Catelleone (CR), Italy

DATE: 8/21/90

COMMENT:

Cerioli writes to comment on the draft's comparison of various modelling techniques for estimating the yearly number of lung cancer deaths due to ETS. The pertinent section is Appendix D of the draft. He discusses the Relative Potency Approach (Approach 1) and concludes that the approach cannot be scientifically supported.

2501361433

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Alfred P. Wehner
Biomedical & Environmental Consultants, Inc.
312 Saint Street
Richland, WA 99352

DATE: 9/94/90

COMMENT:

Wehner, who served as project director/toxicologist at Battelle Pacific Northwest Laboratories from 1967-89, suggests that recent controversy over ETS warrants re-evaluation of data and conclusions. He provides the conclusion of his 1986 study ("Indoor Air Pollution.III. Environmental Tobacco Smoke. MEDICEF Direct Information (ISSN 0258-3763)) and contrasts it with the Surgeon General's Report (The Health Consequences of Involuntary Smoking. U.S. Dept. of Health and Human Services, 1986).

NAME

Richard L. Tweedie, PhD, ScD
Dean
School of Information and Computing Sciences
Bond University
Gold Coast
Queensland 4229
Australia

DATE: 9/24/90

COMMENT:

Tweedie submits a comment based on research carried out at Bond University in the 18-month period preceeding September, 1990. Tweedie points to four flaws in the approach employed in the EPA draft and notes that his research leads to the conclusion "that the human evidence at this time is inadequate to enable a conclusion [on the carginogenicity of ETS] to be reached."

2501361434

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

R.C. Brown
MRC Toxicology Unit
Woodmansterne Road
Carshalton, Surrey, UK

DATE: 9/25/90

COMMENT:

Brown writes to comment on the policy implications of acceptance of the EPA draft. With regard to respiratory disorders in children, Brown feels that "there is enormous scope for more studies on these possibilities and conclusions are not possible at this point." He provides eight comments on the directions that further research might take and on the problems that acceptance of the draft might create.

NAME

John W. Clayton, Jr., PhD, DATS
7762 Harelston Place
Tuscon, AZ 85104

DATE: None

COMMENT:

Clayton writes to point out "the conspicuous absence of any consideration of pertinent toxicological data in the assessment." He feels that both epidemiological and toxicological data must be evaluated in determining whether or not ETS causes lung cancer in humans, and that available toxicological data do not support the classification of ETS as a known human carcinogen.

2501361435

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Jean D. Gibbons, PhD
The University of Alabama
75 Bidgood
Box 870226
Tuscaloosa, AL 35487

DATE: 9/26/80

COMMENT:

Gibbons, a statistician, criticizes the draft's statistical treatment of various issues. Her comments fall into the following categories: (1) Definition of ETS; (2) Sources of Bias in Studies; (3) Reliance on Foreign Studies; (4) Attention Paid to Confidence Levels in Individual Studies; and (5) The Meta-Analysis Approach.

NAME

Domingo M. Aviado, MD
Atmospheric Health Sciences
P.O. Box 307
Short Hills, NJ 07078

DATE: 9/26/90

COMMENT:

Aviado challenges the validity of the "biological plausibility" argument set forth in the draft. His principal reason for rejecting the "biological plausibility" argument is that "suspected carcinogens" in mainstream or sidestream smoke have not been proven as site specific pulmonary carginogens.

2501361436

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Arthur Furst, PhD, ScD, DATS
University of San Francisco
Institute of Chemical Biology
Ignatian Heights
San Francisco, CA 94117

DATE: 9/27/90

COMMENT:

Furst claims that the draft's authors incorrectly apply the criteria for determning human carcinogenicity. He notes that "the epidemiology is not well established; the animal data all showing an opposite effect are not considered." He concludes that there is no scientific evidence to justify the classification of ETS as a Group A carcinogen.

NAME

J.W. Daniel, PhD, DSc, FRC Path
Shortwood
The Ryefield
Essex
CM3 4TR
England UK

DATE: 9/27/90

COMMENT:

Daniel writes that the eivdence presented in the draft does not justify the conclusion that ETS should be classified as a Group A carcinogen. He questions the adequacy of the epidemiological studies relied upon to make the case for Group A classification in the draft, and concludes, "The evidence, at best, is suggestive of only the possibility of a potential risk, rather than an absolute risk."

2501361437

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Nathan Mantel
11508 Regency Drive
Potomac, MD 20854

DATE: 9/27/90

COMMENT:

Mantel writes that the conclusion that passive smoking causes lung cancer is not justified. He feels that meta-analysis of all of the studies cited in the draft is inappropriate. Mantel provides specific comments on the body of the draft and Appendix D. He submits general comments on the quality of the exposure assessment and the estimation of the size of the population at risk.

NAME

Nancy J. Haley, PhD
Metropolitan Life Insurance Company
Associate Director
Insurance Testing Laboratory
4 Westchester Plaza
Elmsford, NY 10523

DATE: 10/1/90

COMMENT:

Haley writes that the draft's section on biomonitoring "fails to adequately differentiate between exposure at home and in the workplace." She attaches three documents which support her criticism.

2501361438

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Theodore D. Sterling, PhD
James J. Weinkam, PhD
Wilfred L. Rosenbaum
Therese M. Poland
Simon Fraser University
Burnaby, BC V5A 1S6

DATE: 9/25/90

COMMENT:

This lengthy comment focuses on criticizing the draft for its statistical analysis of aggregate data and for not fully exploring alternative explanations for increased lung cancer among spouses of smokers. Two papers co-authored by Sterling and Weinkam are attached.

NAME

Gary L. Huber, MD
The University of Texas Health Center
P.O. Box 2003
Tyler, TX 75710

DATE: 10/1/90

COMMENT:

Huber writes to express three concerns. First, he claims the ETS literature database upon which the draft is based is selective and incomplete. Second, he is dissatisfied with the draft's treatment of the physical, chemical, and biological properties of ETS. Third, he asserts that the risk assessment for infants and children passively exposed to smokers is not scientifically supportable. Huber attaches five appendices.

2501361439

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

A. Springall, PhD
Department of Computer Studies and Mathematics
Bristol Polytechnic
Coldharbor Lane
Frenchay
Bristol BS16 1QY
England, UK

DATE: 10/1/90

COMMENT:

Springall concludes that there is insufficient epidemiological evidence to justify the classification of ETS as a Group A carcinogen or to support the estimate of 3,800 nonsmoker deaths per year from lung cancer in the U.S. can be attributed to ETS.

NAME

Ernst L. Wynder, MD
American Health Foundation
320 East 43rd Street
New York, NY 10017

DATE: 10/1/90

COMMENT:

Wynder notes that because of its reliance on meta analysis, the draft pays insufficient attention to inconsistencies among various studies and epidemiological problems. He attaches the Wynder/Kabat paper entitled, "Environmental Tobacco Smoke and Lung Cancer: A Critical Assessment," as well as a copy of Geoffrey Kabat's comments at the 1990 Toxicology Forum.

2501361440

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

J.W. Bridges, BSc, PhD
Director
Robens institute of Health and Safety
University of Surrey
Guildford, Surrey GU2 5XH

DATE: 10/1/90

COMMENT:

Bridges feels that the data presented in the draft appear insufficient to justify the conclusion that ETS should be classified as a Group A carcinogen. He makes five points as follows: (i) the epidemiological studies do not consider sufficiently potential sources of lung irritants other than ETS; (ii) the draft makes a shaky assumption that the population of nonsmokers married to smokers is identical physiologically and psychologically to the population of nonsmokers married to nonsmokers; (iii) the draft does not refer to studies of animal exposure to ETS; (iv) scant reference is made to animal inhalation studies in considering dose response models; and (v) further research is needed on exposure and dosage during the particulate phase of ETS.

NAME

John A. Todhunter, PhD, FAIC, DABT
Science Regulatory Services International
1625 K Street, N.W.
Washington, D.C. 20006

DATE: 10/1/90

COMMENT:

Todhunter concludes the following: (1) low dose extrapolation yields results well within the bounds of uncertainty, rendering EPA's epidemiology-based conclusions unreliable; (2) the proper classification of ETS is in Group D; and (3) comparison of ETS with prior EPA carcinogen classifications requires a Group D classification of ETS.

2501361441

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DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Edward L. Alpen
1182 Miller Avenue
Berkeley, CA 94708

DATE: 10/1/90

COMMENT:

Alpen comments on the epidemiological evidence presented in the draft. He feels that meta-analysis is used appropriately, but that not enough attention is given to the shortcomings associated with meta-analytic method. He also notes that the Gillis study (1984) should be considered along with those of Garfinkel (1985) and Hirayama (1984). Alpen concludes that the draft is "seriously flawed as a basis for federal regulatory action." He recommends that the SAB conduct a more complete review of data and issue a report similar to the McGill Report of 1989.

NAME

Peter N. Lee, MA
Lee Statistics and Computing Ltd.
17 Cedar Road
Sutton, Surrey SM2 5DA
England, UK

DATE: 10/1/90

COMMENT:

Lee provides an extensive comment on the draft's statistical grounding. In summary, he feels that "the report has a large number of flaws which make it unacceptable." He attaches a copy of his own draft review document entitled, "A detailed review of epidemiological evidence relating ETS to the risk of cancer, heart disease and other causes of death in adults who have never smoked."

2501361442

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DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Joseph M. Wu, PhD
New York Medical College
Valhalla, NY 10595

DATE: 10/1/90

COMMENT:

Wu comments on Chapter 5 of the draft. In short, Wu concludes that the studies utilized in the draft do not "adequately consider the numerous significant environmental factors that could confound reported associations between children's respiratory disorders and exposure to ETS."

NAME

Joseph L. Fleiss, PhD
Columbia University
School of Public Health
New York, NY 10032

and

Allan J. Gross, PhD
Medical University of South Carolina
Charleston, SC

DATE: 10/1/90

COMMENT:

Fleiss and Gross criticize the draft for its use of meta-analysis. They claim that many flaws found in the 1986 National Research Council and Surgeon General's reports have been carried over into the draft. They suggest that even if each of the individual studies cited were valid, EPA's use of meta-analysis would undermine the overall validity of the assessment.

2501361443

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DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Alan W. Katzenstein, MBA
Katzenstein Associates
Larchmont, NY 10538

DATE: 10/1/90

COMMENT:

Katzenstein comments on the draft's findings that approximately 3,800 American nonsmokers die from ETS each year and that passive smoking is causally associated with lung cancer. He discusses at length the presence of confounding factors in assessing epidemiological studies of cancer, providing many examples of confounders which invalidate the draft's findings.

NAME

Paul Switzer, PhD
Department of Statistics
Stanford University

DATE: 10/1/90

COMMENT:

Switzer comments on the question of whether exposure to ETS causes cancer in the U.S., at the request of the Tobacco Institute. He contends that the draft "fails to measure up to the five risk assessment criteria that it purports to apply to the epidemiologic data base on ETS and lung cancer." He goes on to comment specifically on several of the draft's conclusions.

2501361444

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DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Jarnail Singh, PhD
Stillman College
P.O. Box 1430
Tuscaloosa, AL 35403

DATE: 10/1/90

COMMENT:

Singh comments on the following: (1) the draft's characterization of the 1986 Surgeon General's Report; (2) the validity of the studies cited in the draft; and (3) the role of confounding factors not adequately addressed in the draft. He notes that most studies report that the pulmonary function of children of smoking parents is within the normal range. He notes that any reported deficits in pulmonary function are attributable to the combined effects of a variety of factors.

NAME

F.J. Roe, DM, DSc, FRC, Path., FATS
19 Marryatt Road
Wimbledon Common
London SW19 5BB
England, UK

DATE: 10/1/90

COMMENT:

Roe finds it "particularly surprising" that the draft regards data from the Hirayama study as more reliable than data from the Garfinkel study. He feels that with regard to the question of ETS-lung cancer causality, "the only safe conclusion that can be based on the available evidence is that it remains unclear whether there is any lung cancer risk from exposure to other people's smoke and that if there is any such risk there is absolutely no reliable way to quantify it."

2501361445

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DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

S. James Kilpatrick Jr., PhD
Medical College of Virginia
Virginia Commonwealth University
Richmond, VA 23298

DATE: 10/1/90

COMMENT:

Kilpatrick writes to comment on the 1984 Hirayama study. He is generally critical of the study's validity. Kilpatrick evaluates the Hirayama study in light of six papers: Layard & Viren (1989), Uberla & Ahlborn (1987), Ahlborn and Uberla (1988), and three Kilpatrick papers. Kilpatrick finds it "paradoxical that the Hirayama study, whose raw data have never been released, is used here as a gold standard to evaluate a study whose data have been released."

NAME

Mark J. Reasor, PhD
1153 Cambridge Avenue
Morgantown, WV 26505

and

James A. Will, DVM, PhD

DATE: 10/1/90

COMMENT:

Reasor and Will criticize the draft on the grounds that it characterizes ETS insufficiently and that the extrapolations from mainstream smoke exposure to ETS exposure are, therefore, problematic.

2501361446

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Joe Pedelty, MSc
Holcomb Environmental Services
17375 Garfield Road
Olivet, MI 49076

DATE: 10/1/90

COMMENT:

Pedelty states that the draft makes five major assumptions about ETS, none of which is supported by available data. Thus, he contends the risk assessment of ETS is not credible.

NAME

Ronald D. Hood, PhD
The University of Alabama
Box 870344
Tuscaloosa, AL 35487

and

Raphael J. Witorsch, PhD
Philip Witorsch, PhD

DATE: 10/1/90

COMMENT:

Hood, Witorsch, and Witorsch comment on the reported association between parental smoking and specific respiratory health end points addressed in the draft. They provide a 60 page summary of their findings and conclude that the draft's statement that "passive smoking in early childhood is associated with decreased lung function in childhood and with a small reduction in their rate of pulmonary growth and development" is not substantiated by the data presented.

2501361447

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Dr. G. B. Gori
The Health Policy Center
6704 Barr Road
Bethesda, MD 20816

DATE: 10/1/90

COMMENT:

Gori writes, "By any measure of fairness, the EPA draft is not a scientific analysis." He faults the draft for its exclusion of studies, use of one-tailed statistical probabilities, treatment of dose-effect gradients, failure to consider many potentially confounding factors, and other deficiencies.

NAME

John M. Faccini, MD
Les Ouldes
Francueil 37150
Blere, France

DATE: 10/1/90

COMMENT:

Faccini, a histopathologist, feels that the absence of substantial histopathological confirmation of the diagnosis of primary lung cancer in many cases cited in the draft is problematic. He also notes that the draft fails to give adequate consideration to the cluster of cases of adenocarcinoma of the lung among Chinese women. Faccini attaches his 1989 paper entitled, "The Role of Histopathology in the Evaluation of Risk of Lung Cancer from Environmental Tobacco Smoke."

2501361448

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

J.W. Gorrod, PhD
University of London
Chelsea Department of Pharmacy
London SW3 6LX
England, UK

DATE: 10/1/90

COMMENT:

Gorrod comments on several items presented in Appendix C which pertain to the dosimetry of ETS. in general, he feels that the draft is flawed because it lacks meaningful data and uses nicotine "as though nicotine was a marker of the passage of ETS through a biological system."

NAME

Salvatore R. DiNardi, PhD
PHRA, Incorporated
223 Pomeroy Lane
Amherst, MA 01002

DATE: 10/1/90

COMMENT:

DiNardi criticizes the draft for implying that the sole indication of ETS exposure is the presence of nicotine in air samples or nicotine and cotinine in bioassay. He critiques the six conclusions presented in the Executive Summary and comments on the composition of ETS; the differences between SS, MS, and ETS; and the basic exposure assessment.

2501361449

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Howard Goodfellow, PhD, PE

and

Susan Eyre, MHSc
Goodfellow Consultants, Inc.
2000 Argentina Road
Plaza III
Suite 301
Mississauga, Ontario
L5N 1V9 Canada

DATE: 10/1/90

COMMENT:

Goodfellow and Eyre fault the EPA for failing to include the results of many studies in the draft. Their comment concentrates on uncertainties in the realm of ETS exposure assessment.

NAME

George Feuer, PhD CMedSc
Department of Clinical Biochemistry
University of Toronto
Toronto M5G 1L5
Canada

DATE: 10/1/90

COMMENT:

Feuer criticizes the draft for its reliance on studies which are inconsistent and preliminary. He concludes that a causal relationship between ETS and lung cancer has not been established.

2501361450

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Alan J. Gross, PhD
Medical University of South Carolina
171 Ashley Avenue
Charleston, SC 29425

DATE: 10/1/90

COMMENT:

Gross comments primarily on Chapters 3 and 4 of the draft. He concludes that (1) the risk assessment is based upon studies for which proper controls were not employed, (2) the meta-analysis of studies was improper, and (3) the contention that a causal link between ETS and lung cancer exists cannot be supported.

NAME

Donald J. Ecobichon, PhD
McGill University
3655 Drummond Street
Montreal, PQ H3G 1Y6
Canada

DATE: 10/1/90

COMMENT:

Echobichon submits information from the 1989 McGill Symposium on ETS and attaches a copy of the book containing the McGill proceedings.

2501361451

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Lawrence M. Wexler, PhD
1 Lincoln Plaza
Apartment 18D
New York, NY 10023

DATE: 10/1/90

COMMENT:

Wexler suggests that several key variables must be examined before any conclusions can be established regarding a causal relationship between ETS and lung cancer, and he faults the draft for its inadequate treatment of associated issues.

NAME

Maurice E. LeVois, PhD
Maxwell W. Layard, PhD
Environmental Health Resources
Four Embarcadero
Suite 2000
San Francisco, CA 94111

DATE: 10/1/90

COMMENT:

LeVois and Layard provide a lengthy comment which concludes that the observed epidemiologic association between ETS exposure and lung cancer is weak and inconsistent. They also find that the design and conduct of the relied-upon ETS studies are weak.

2501361452

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Edward J. Faeder, PhD, REA
Senior Vice President
The Jefferson Group, Inc.
100 North Barranca Avenue
Suite 700
West Covina, CA 91791

DATE: 10/2/90

COMMENT:

Faeder submits a five-page comment. His comment is a critique of EPA's four-step carcinogen classification process. He contends, ". . . each of the four steps EPA identified for carcinogenic risk assessment has inherent flaws in its application to ETS." He concludes that EPA lacks sufficient evidence to classify ETS as a known human carcinogen.

NAME

W.H. Butler, PhD
The British Industrial Resource Association
Woodmansterne Road
Carshalton Surrey SM5 4DS
UK

DATE: 10/2/90

COMMENT:

Butler submits that toxicological/biological considerations render extrapolation from the population of female non-smoking spouses of male smokers to the general population uncertain. Butler also claims the evidence does not support Group A classification of ETS.

2501361453

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Dennis Paustenbach, PhD, DABT
Chem Risk
1135 Atlantic Avenue
Alameda, CA 94501

DATE: 10/2/90

COMMENT:

Paustenbach writes that EPA's conclusion that passive smoking causes lung cancer in adults is not sufficiently substantiated. He feels that meta-analysis is employed inappropriately and that the scientific information necessary for conducting a health risk assessment sufficient to justify a regulatory standard is not available. He goes on to comment on specific sections of the draft.

NAME

Anthony V. Colucci, ScD
Colucci and Associates, Inc.
823 W. Fifth Street
Winston-Salem, NC 27101

DATE: 10/2/90

COMMENT:

Colucci discusses many problematic issues in the draft. The most important flaw, he claims, "Is the Agency's failure to recognize the fact that no reliable quantitative indicator of ETS exposure underpins the epidemiologic data collected to date." He concludes that the draft is biologically implausible.

250136145 4

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

William J. Butler, PhD
Failure Analysis Associates
149 Commonwealth Drive
P.O. Box 3015
Menlo Park, CA 94025

DATE: 10/2/90

COMMENT:

Butler's review of the draft addresses EPA's consideration of lung cancer and exposure to ETS. He finds that available epidemiologic information does not satisfy EPA's guidelines for the identification of ETS as a known human carcinogen. Furthermore, he notes the hazard identification section of future revisions of the draft must consider evidence from scientific areas in addition to epidemiology, and that the review of epidemiologic evidence should not be restricted to statistical examinations of data.

NAME

E. Lee Husting, MPH, PhD, FACE
P.O. Box 76350
St. Petersburg, FL 33734

DATE: 10/2/90

COMMENT:

Husting submits an epidemiological review of the draft. He concludes that the draft "is as much argumentative as analytical, and is based on arbitrary assumptions." He is particularly concerned that EPA has not followed the Risk Guidelines Criteria and erroneously classified ETS as a Group A carcinogen.

2501361455

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Frank M. Sullivan
Department of Pharmacology
Guy's Hospital Medical School
London Bridge SE1 9RT
London, UK

DATE: 10/3/90

COMMENT:

Sullivan, who has researched the reproductive toxicity of chemicals for the past 30 years, feels that the section on passive smoking and respiratory disorders in children "is neither complete nor well-balanced." He suggests changing the title of the document to "Health Effects of ETS" to avoid confusion between passive smoking and passive exposure of a fetus in utero to tobacco. He provides a three page list of pertinent references not quoted by EPA to complement his seven page comment.

NAME

Peter Skrabanek, MD
University of Dublin
Trinity College
Dublin 2 Ireland

DATE: 10/3/90

COMMENT:

Skrabanek criticizes the draft on the grounds that (1) many of the studies included in EPA's meta-analysis used women in Asia as subjects, (2) EPA does not attempt to assess the extent of detection bias, (3) EPA does not address the issue of adenocarcinomas in non-smoker cases alleged to have developed lung cancer from ETS, (4) the draft leaves serious problems of biological plausibility unresolved, and (5) the classification of ETS as a known human carcinogen is the result of an extrapolation fallacy.

250136145 6

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

T. Malmfors, MD, PhD
Malmfors Consulting AB
Bedomning av Kemiska Halsorisker
Kammakargatan 48
S-111 60 Stockholm, Sweden

DATE: 10/4/90

COMMENT:

Malmfors feels that the draft does not provide a representative view of the present state of the scientific literature on ETS. He also believes that EPA classifies ETS as a Group A carcinogen without sufficient evidence. Finally, Malmfors asserts that EPA's methods of estimating the total number of lung cancer deaths per year in the U.S. are highly questionable.

NAME

David A. Weeks, MD
P.O. Box 1761
Boise, ID 83701

DATE: 10/4/90

COMMENT:

Weeks writes to express the thought that ETS exposure reduction research is a "misallocation of scarce scientific and public health resources."

2501361457

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

D. Schmähl, PhD
Geschäftsführender Direktor des Instituts für
Toxikologie und Chemotherapie
Deutsches Krebsforschungszentrum
6 900 Heidelberg
Im Nevenheimer Feld 280
Durchwahl 484300

DATE: 10/5/90

COMMENT:

Schmähl cautions EPA against presenting quantitative analyses on bronchial cancer and passive smoking without "a really unassailable basis" for assessment. He also questions EPA's definition of passive smoking and notes that the draft fails to consider the fact that histologic evidence of lung cancer is missing in most of the epidemiologic studies.

NAME

Karl Jonas, MD
4920 Sentinel Drive
Bethesda, MD 20816

DATE: 10/10/90

COMMENT:

Jonas writes that the studies considered in the draft are inconsistent, contradictory, and inconclusive. He questions the classification of ETS as a Group A carcinogen and claims that the draft's conclusions on respiratory symptoms and respiratory infections in children of smoking parents are not supported by scientific evidence.

2501361458

Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000

DRAFT RISK ASSESSMENT PUBLIC COMMENTS (Continued)

NAME

Larry C. Holcomb, PhD
Holcomb Environmental Services
17375 Garfield Road
Olivet, MI 49076

DATE: 10/19/90

COMMENT:

Holcomb writes that mortality risk from ETS as reported by EPA has no scientific value because it is not based on the principles of risk assessment. He claims that EPA's dose-response modeling is "highly suspect," and that there is no evidence of adverse health impacts to either children or adults from ETS exposure.

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Source: https://www.industrydocuments.ucsf.edu/docs/yswk0000